PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference see form PCT/ISA/220	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/022051	15.10.2007	17.10.2006

International Patent Classification (IPC) or both national classification and IPC
INV. G06F19/00

Applicant
SMITHS MEDICAL MD, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Chabros, Cezary Telephone No. +49 89 2399-6094

Form (PCT/ISA/237) (Cover Sheet) (April 2005)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-58
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-58
Industrial applicability (IA)	Yes:	Claims	1-58
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following document:
D1: US 2005/171513 A1 (MANN ALFRED E [US] ET AL) 4 August 2005
D2: US 2003/163088 A1 (BLOMQUIST MICHAEL L [US]) 28 August 2003

2. **Article 33(3) PCT**

2.1 The application contains 5 independent claims, out of which claims 1 and 17 are directed to methods of programming a pump and claims 43, 48, 54 are directed to insulin pumps.

The assessment of whether any of the above claims meets the requirements of Article 33(3) PCT will be started from the assessment of whether the subject-matter of claim 54 meets requirements of Article 33(3) PCT due to the following reasons:

Claim 54 defines a superset of features defined by the remaining independent claims, with the exception of the feature "display" of claims 43 and 48. However, this feature is disclosed in the closest prior art document D1 and therefore does not represent a distinguishing feature.

2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 54 does not involve an inventive step in the sense of Article 33(3) PCT.

2.3 The document D1 is regarded as being the closest prior art to the subject-matter of claim 54:

Claim 54	corresponding features in D1
An insulin pump comprising: a pump mechanism;	fig.1, items 32, 34, 36
a memory configured to store a plurality of screens used in programming the pump, the plurality of screens including a first screen and a second screen,	fig.1, item 22 fig.8(a); paragraph 143
the memory further configured to store a plurality of sounds including a first sound and a second sound;	paragraphs 60-61
a programmable circuit arranged to control the pump mechanism and operatively connected to the memory, the programmable circuit programmed to:	fig.1, item 18
provide an up key and a down key for selecting a current value from an operational range having an upper threshold value and a lower threshold value;	paragraphs 60-61: up key for selecting a value paragraph 152: threshold values for meal bolus size and maximum basal rate
assign the first sound to the up key; assign the second sound to the down key, the second sound different from the first sound; upon detection of activation of the up key, emit the first sound; and upon detection of activation of the down key, emit the second sound; wherein the first sound has a higher pitch than the second sound	paragraphs 60-61: different sounds are assigned to different keys

2.4 The subject-matter of claim 54 differs from D1 in :
- the provision of two keys instead of one key to be able to scroll up and down in an allowed range, vs. the possibility to scroll only up in an allowed range,

- the provision of lower and upper thresholds instead of only lower thresholds.

The above distinguishing features however represent obvious alternative implementation details of a user interface of an infusion pump.

With reference to the first distinguishing feature, the following is pointed out: The increase of user-friendliness of the human-machine interface (HMI) of the insulin pump by enabling a scrolling through the allowed value range in the up and down direction instead of scrolling in only one direction represents a standard HMI design option and would be an obvious implementation alternative for a skilled person.

The implementation of this standard, well known HMI design option is disclosed in an insulin pump in document D2, paragraph 177.

2.5 With reference to the second distinguishing feature (the provision of lower and upper thresholds instead of only lower thresholds), the following is pointed out: The necessity to disallow the user to select values lower than a predetermined value would in an obvious manner lead the designer of the insulin pump to provide in addition to the upper threshold value also a lower threshold value. However, the decision to disallow the selection of values lower than a predetermined value is not a technical consideration, but a therapeutical decision of a medical professional. As a non-technical feature, it cannot provide a technical contribution over the prior art and hence, cannot confer an inventive step to the claimed subject-matter.

It is pointed out that both distinguishing features discussed above taken individually do not confer an inventive step to the claimed subject-matter. However, both above distinguishing features also do not provide an inventive step when considered in combination, since the combination of these features does not provide any unexpected technical effect which would go beyond the simple sum of the effects provided by said features individually.

Consequently, the subject-matter of claim 54 lacks inventive character and, hence, does not fulfill the requirements of Articles 33(1) and 33(3) PCT.

2.6 Claims 1 and 17 are method claims which define uniquely features corresponding to the features of independent apparatus claim 54 discussed above, arranged in the same order and providing the same effects. When considering the similarities in structure, the same objection of lack of inventive step raised for the subject-matter of independent claim 54 do apply in their entirety, mutatis mutandis, also to the subject-matter of claims 1 and 17.

2.7 Since independent apparatus claims 43, 48 define uniquely features corresponding to the features of independent apparatus claim 54 discussed above (i.e. a subset of features),and furthermore these features are arranged in the same order and are providing the same effects, the same objection of lack of inventive step raised for claim 54 applies also to the subject-matter of these claims.

2.8 The subject-matter of the dependent claims seems to differ from the discussed independent claim 54 only in features which do not provide any **technical** contribution over the closest prior art or define obvious implementation details. Therefore, they do not meet the requirements of the PCT in respect of inventive step.